**CENTRAL ADELAIDE LOCAL HEALTH NETWORK**

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| **Human Research Ethics Committee Submission Covering Letter**  **Investigator Initiated Clinical Trials** | | | |
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| This form must be completed by the coordinating Principal Investigator (CPI) for all multi-site projects or the Principal Investigator (PI) for single site projects when submitting a new Investigator Initiated Research study to the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) for ethical and scientific review. Asterisks denote mandatory fields. Upload as supplementary document via Research GEMS. For low negligible risk research applications see submission requirements here (<https://www.rah.sa.gov.au/research>) | | | |
| 1. **PROJECT OVERVIEW\*** | | | |

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| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | CPI Name: Enter text | | | | | | | | \*Program: Enter text | | \*Department: Enter text | | | | | | Project Category: Choose an item. | | Phase:Enter text | | | \*CTN/CTA Choose an item. | | | Study title: Enter text | | | | | | | | \*Institution responsible for protocol/results ownership: Enter text | | | | | | | | Study Site/s | Public  Private | | State | Site Principal Investigator | | | Enter text | Enter text | | Enter text | Enter text | | | Enter text | Enter text | | Enter text | Enter text | | | Enter text | Enter text | | Enter text | Enter text | | | Enter text | Enter text | | Enter text | Enter text | | |
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| 1. **RADIATION** |
| All research involving any form of radiation must comply with relevant National and State legislation, organisational policies and procedures, and codes and standards of practice provided by the NHMRC and the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).  SA Medical Imaging now has online system to determine if you will be required to submit a Radiation Safety Report for your study.  You can access the new form via [https://redcap.link/SAMIethicsrequest](https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fredcap.link%2FSAMIethicsrequest&data=05%7C01%7CHealth.CALHNResearchEthics%40sa.gov.au%7C50842f265183491c924808dbb8b8811e%7Cbda528f7fca9432fbc98bd7e90d40906%7C1%7C0%7C638306874794731360%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nmJ9lSnVVzQSElhoaosumjVdEAyN8D%2BXu9qymBuAJck%3D&reserved=0) - enter your contact details and you will receive an email with a link to the new form.  Provide a copy of the outcome of your REDCap submission as part of your submission to CALHN HREC. (Either a copy of the email stating you do not require Radiation Safety Report or a copy of the Radiation Safety Report) If multisite a radiation report or a standard of care statement must be provided for **all** sites.  *If you have troubles with accessing the REDCap system contact SA Medical Imaging at* [*radiationsafety@sa.gov.au*](mailto:radiationsafety@sa.gov.au)  **\*JUSTIFICATION IF RADIATION IS STANDARD OF CARE**  That is, if a patient was not enrolled in the above study, they would still receive an equivalent number of exams involving the use of ionising radiation at the specified intervals as stated in the research protocol. In making this determination investigators have considered:   1. The body region being examined. 2. The modality being identical to that used as part of standard care. 3. Frequency or number of the exams proposed. 4. Differing cancers of potential patients.  |  | | --- | | \*Provide a justification statement (include number of exams involving the use of ionising radiation Enter text | |
| 1. **THERAPEUTIC GOODS ADMINISTRATION (TGA) CLINICAL TRIAL NOTIFICATION/APPROVAL SCHEME** |
| The Therapeutic Goods Administration (TGA) must be notified of clinical trials of unapproved therapeutic goods via the Clinical Trial Notification (CTN) scheme or the Clinical Trial Approval (CTA) scheme.  If you intend to conduct an investigator-initiated clinical trial of an unapproved therapeutic good and CALHN is the sponsor, please refer to the information on the TGA website [“Which clinical trial scheme should I use”](https://www.tga.gov.au/resources/which-clinical-trial-scheme-should-i-choose) to determine if a CTN or a CTA is required.  If a CTN is required please contact CALHN Research Services via [Health.CALHNClinicalTrials@sa.gov.au](mailto:Health.CALHNClinicalTrials@sa.gov.au) who will submit the CTN for you.  If a CTA is required, please follow the [TGA CTA instructions](https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.tga.gov.au%2Fclinical-trials%23cta-scheme&data=05%7C01%7CJan-Louise.Durand%40sa.gov.au%7C7a21309419a94f33525208dbf55c3dc0%7Cbda528f7fca9432fbc98bd7e90d40906%7C1%7C0%7C638373548742348093%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=pKTGwcbN0JPqPxyB1GcfOICUlGcf%2FVASYc8NtPaRKSk%3D&reserved=0). |
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| 1. **INVESTIGATOR STATEMENT\*** |

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| The Investigator Statement must be submitted together with the protocol submission. The following questions must be addressed in the statement. | | | |
| **\*What is the current standard treatment for this patient population at CALHN/NALHN?** | | | |
| Enter text | | | |
| **What are the overall benefits to the project participant?** | | | |
| Enter text | | | |
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| **What are the risks to the project participant?** | | | |
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